

**REMARKS**

This amendment adds claims 28-31 and amends claims 1, 2, 15, and 27. Claims 1-16 and 27-31 are pending following entry of this amendment.

The Office Action rejected claim 27 as being indefinite for the use of the word "several". Claim 27 now claims "more than one" and this rejection is respectfully traversed, as the claim is not indefinite.

The Action also rejected claims 1 and 2 (and their dependent claims) as containing subject matter not disclosed in the specification. Specifically, the Action argues that the disclosure does not show an *entire* blank heated *outside* the negative mold. But the specification does support this language. In the paragraph bridging pages 14 and 15, the blank is described as "brought into the first heating stage 9, pre-heated accordingly there, heated further in the heating stage 10, *and then* formed in the negative mold in the region of stage 11." Heating of the blank is manifestly done *outside* the mold. The specification elaborates at another point. "In this process, the blank is brought to a corresponding temperature (dough-like or honey-like flowing consistency) *and then* pressed into a negative mold." Page 17, first full paragraph. Finally, in Figure 6 (and the accompanying description at pages 18-19), the blank is heated in sections 9 and 10, and *then* pressed into the mold 13. Thus the blank is evidently heated *outside* of the mold. So, with reference to each of the above portions of the specification and Drawings, the specification supports the

claim language: "heating the entire blank...outside of the negative mold", and the § 112 rejection is respectfully traversed.

Independent claims 1 and 2 were also rejected under 35 U.S.C. § 103 over EP 0 373 294 and JP 02-145327, both in view of U.S. Pat. No. 3,850,723 to Ackley. EP 0 373 294 shows a method for producing screws for use in the aircraft industry. According to the specification, plastic screws are suited for use in the manufacture of airplane components due to their lightweight and moisture resistant properties. JP 02-145327 describes a nylon resin and braided yarn reinforced screw that is formed in a mold and axially compressed by a punch. Ackley shows a method for forming resin-fiber sheets.

The proposed combination of axially-pressure formed screw references (EP 0 373 294 and JP 02-145327) with a process of forming sheet material for use in a stamping process (Ackley) is unwarranted. A combination of references is only proper when there is a suggestion to combine the references and a reasonable expectation of success in combining them. Neither criterion is met here. There is no suggestion within the references themselves for their combination. Regarding the combination of Ackley with either of the other references, there is no suggestion to combine the stamping and molding arts, especially because one of ordinary skill in the art would recognize the shortcomings of using a stamping process in forming precision medical screws. Further, one of ordinary skill in the art would be hard-

pressed to look to the process of forming sheet material (Ackley) when forming reinforced screws, especially since the problem that is being overcome in the screw formation is how to reinforce the molded, that is *not stamped*, threads. There is also no reason one of ordinary skill would think that the simple process of mat forming (Ackley) would yield any expectation of success in the art of screw and screw-thread formation. Regarding the combination of Ackley with EP 0 373 294, there is no suggestion to combine the mat forming and the aircraft rivet arts to render obvious the claimed invention that relates to medical screws. Since there is no suggestion to combine the references and no reasonable expectation of success in combining them, the combination is unwarranted and should be withdrawn, together with the accompanying rejections based thereon.

The prior art references in combination, and individually, do not teach or suggest what is now claimed in the application. As was repeatedly recognized in the Office Action, neither of the primary references (JP 02145327 and EP 0 373 294) shows a heating step that occurs outside the mold, as is now claimed. Even the Ackley reference, which the Action cites as teaching this step, does not. Ackley teaches applying pressure to multiple resin and mat layers within a mold and *then* heating the layers to form a sheet. Col. 6, line 60 to Col. 7, line 6. So in the process taught by Ackley, the heat is added *after* the sheets are in the press and pressure is applied. This is the opposite of what is claimed, namely, that the blank is heated "to

a forming temperature with plastic flow consistency in a heating stage located outside the negative mold”.

The “preheating” referred to in Ackley has to with using the sheet post-production. Ackley describes preheating a formed sheet prior to its final stamping into a product. A careful reading of Ackley shows that the preheating precedes final *stamping* of a product, as opposed to the claimed molding. Col. 6, lines 1-21. Such a stamping process would yield burrs and other irregularities that are unacceptable in medical devices, .

To the extent Ackley shows any preheating, it does not preheat the mat-resin layers to a “forming temperature with a plastic flow consistency”. The Action claims that Ackley teaches heating the “blank to a soft flowable state outside the mold”, but Ackley teaches no such thing. Action at page 5. The goal of Ackley is forming a layered sheet. If Ackley set out to do what the Action says it does, namely to induce in the sheets a “plastic flow consistency”, the sheet layers would warp and mix, which is clearly not Ackley’s goal, as Ackley seeks a layered sheet. But even more importantly, again, Ackley does not discuss heating the blank to a soft flowable consistency, as is now claimed.

Since Ackley’s heating is not “outside” the mold, the passing reference to a stamping process has nothing to do with the molding process in the current application. There is no mention in Ackley of the type of preheating claimed and

therefore, the combination of Ackley with the other references does not render the claims rejected thereon obvious.

Turning now to the other claim rejections of the dependent claims, it is submitted that since the combinations with Ackley are unwarranted as discussed above, the dependent claims are non-obvious as depending from allowable base claims (1 and 2).

Moreover claim 2 has been rejected as obvious over EP 0 373 294 combined with Ackley. According to the Action, "70% by weight is more than 50% by volume." Since the Action does not provide the supporting densities to back up this statement, this rejection is without foundation and should be withdrawn.

Claim 7 was rejected as obvious over EP 0 373 294 combined with Ackley. The Action does not state that EP 0 373 294 shows a push-pull process, but that is what is claimed. Such a process is not shown in EP 0 373 294, and therefore, the rejection is unwarranted.

Claim 2 was also rejected as obvious over JP 02-145327 combined with Ackley. According to the Action, "70% by weight is more than 50% by volume." As noted above, the Action does not provide the supporting densities to back up this assertion, therefore, this rejection is unwarranted and should be withdrawn.

Claim 7 was also rejected as obvious over JP 02-145327 combined with Ackley. The Action does not state that JP 02-145327 shows a push-pull process, but

that is what is claimed. Such a process is not shown in JP 02-145327, and therefore, the rejection is unwarranted.

Claim 15 was rejected based on a combination of three references: EP 0 373 294 in view of Ackley, and further in view of Gapp. The Action states that the press-speed is a "conventional result-effective variable" citing In re Antoine, 559 F.2d 618 (CCPA 1977) for support. But In re Antoine states that "We have found exceptions to this rule in cases where the results of optimizing a variable, which was known to be result effective, were unexpectedly good." Claim 15's press speed yields an unexpectedly good result and the press-speed contributes to the good result. None of the references teach the optimum results found in the range of 2mm/sec to 8 mm/sec (and supported in the Specification at page 15), as is now claimed.

Claim 9 was rejected over EP 0 373 294 in view of Ackley, further in view of Lee. Claim 9 claims a further step of a carbon or graphite release agent. Lee teaches the use of a fluorocarbon release agent (col. 2, lines 35-40). This reference is inapplicable to reject claim 9 because fluorocarbons are not biocompatible or stable at differing temperatures involved in the molding process. Lee would be ineffective in the process taught in claim 9. Thus, Lee fails to teach what is claimed in claim 9.

Ackley is further differentiated from claims 28-32 in that the claims specify a rod-shaped blank as opposed to Ackley's blanks in sheet form.

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**Application No.:** 08/849,746

For the above reasons, all of the currently pending claims are believed patentable over the prior art. Reconsideration and allowance of the claims is respectfully requested.

If the Examiner believes that a telephone conference with the undersigned will advance the prosecution of this application, please call the undersigned.

Respectfully submitted,

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